DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021264/S-009

SUPPLEMENT APPROVAL

Ipsen Limited
c/o Biomeasure Incorporated
Attention: Steven Scott
Senior Director, US Regulatory Affairs
27 Maple Street
Milford, MA 01757

Dear Mr. Scott:

Please refer to your supplemental new drug application dated December 4, 2009, received December 7, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for APOKYN (apomorphine hydrochloride and Apomorphine hydrochloride injection).

We acknowledge receipt of your additional submission dated January 29, 1010.

This "Prior Approval" supplemental new drug application provides for the changes requested by the Division in a teleconference on February 2, 2009, regarding the Hallucinations/Psychotic-Like Behavior section.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 021264/S-009.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Stacy Metz, PharmD, at (301) 796-2139.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21264	SUPPL-9	IPSEN BIOPHARM LTD	APOKYN

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
09/02/2010